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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,767	04/07/2005	Rajinder Singh	02-438-B1	9966

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EXAMINER

FREISTEIN, ANDREW B

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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06/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,767	Applicant(s) SINGH ET AL.	
	Examiner Andrew B. Freistein	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25,28-34 and 38-46 is/are pending in the application.
- 4a) Of the above claim(s) 38-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25,42 and 43 is/are rejected.
- 7) ☒ Claim(s) 28-34 & 42-46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1626

DETAILED ACTION

The amendment filed 6/4/2007 was entered. Claims 25, 28-34 and 38-46 are pending. Claims 1-24, 26, 27 and 35-37 were cancelled.

Restriction Requirement

Under MPEP 803.02:

Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The examination will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action can be made final unless the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p). See MPEP § 706.07(a).

In the instant case, the amendments overcome the 35 USC 102(b) rejection, but necessitate a rejection under 35 USC 103(a). Therefore, the restriction requirement is maintained and made FINAL.

Status of the Claims

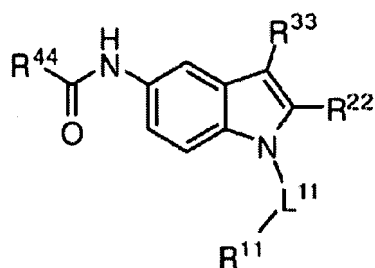
Claims 25 and 28-34 (in part) are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR § 1.142(b). The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference that anticipates one invention would not render obvious the other invention.

Art Unit: 1626

Elected and Examined Subject Matter

The scope of the invention of the elected subject matter and the examined subject matter is as follows:

Compositions comprising compounds of the Formula (I),



, wherein:

L¹¹ is a bond;

R¹¹ is H;

R²² and R³³ are as defined in claim 25; and

R⁴⁴ is an optionally substituted C₃₋₆ monocyclic heteroaryl containing at least one N, O or S atom; or an optionally substituted C₃₋₆ monocyclic heterocycle containing at least one N, O or S atom;

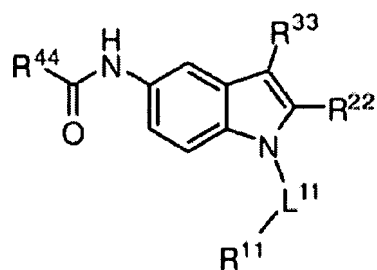
R⁵⁰, R⁶, R⁷ and R²³ are each independently as defined in claim 25.

Non-elected and Non-examined Subject Matter

The scope of the invention of the non-elected and non-examined subject matter is as follows:

Art Unit: 1626

Compositions comprising compounds of the Formula (I),



, wherein:

L¹¹ is carbonyl;

R¹¹ is phenyl or C₄₋₆-heteroaryl;

R⁴⁴ is independently H or optionally substituted C₁₋₆ alkyl, C₃₋₇cycloalkyl, C₃₋₇ monocyclic aryl, C₃₋₇ heterocycloalkyl, C₃₋₇ cycloalkanone, C₇₋₁₃ bicyclic aryl, C₅₋₁₃ bicyclic heteroaryl, C₅₋₁₃ bicyclic heterocycle.

As a result of the election and the corresponding scope of the invention, identified supra, the remaining subject matter of Claims 25-35 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups such as thiophene, furan, phenyl, pyridine, cyclopropane, etc. which are chemically recognized to differ in structure, function, and reactivity.

Therefore, the subject matter which was withdrawn from consideration as being non-elected subject matter materially differs in structure and composition from the elected/examined subject matter so that a reference which anticipates the elected/examined subject matter would not render obvious the non-elected subject matter.

Pending Claim Rejections - 35 USC § 102

(1) Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Johnson et al., WO 98/06402. As a result of the amendment to variable R²² to be C₁₋₆alkyl and not H, the rejection is withdrawn.

(2) Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Bartlett et al., US Pat. No. 5,494,911. As a result of the amendment to variable R²² to be C₁₋₆alkyl and not H, the rejection is withdrawn.

(3) Claim 25 is rejected under 35 U.S.C. 102(e) as being anticipated by Frederickson et al., US 2005/0124620 A1. As a result of the amendment to variable R²² to be C₁₋₆alkyl and not H, the rejection is withdrawn.

Pending Claim Rejections - 35 USC § 112

Claims 30-34 recites the limitation "pharmaceutical composition." There was insufficient antecedent basis for this limitation in the claim, because claim 25 is a "composition." As a result of the amendment filed 6/4/6007, the rejections are withdrawn.

New Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

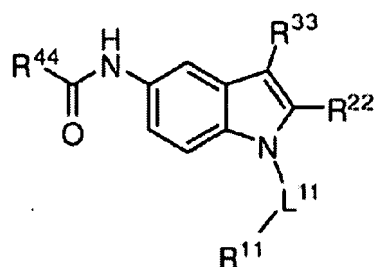
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(1) Claims 25, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al., WO 98/06402.

The instant invention is drawn to a composition comprising a pharmaceutically acceptable carrier, excipient or diluent together with a compound of the formula,

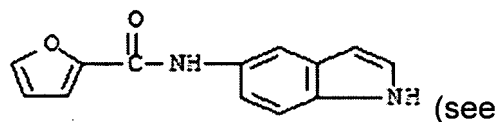


, wherein L^{11} is a covalent bond; R^{11} is H; R^{22} is C_{1-6} alkyl;

R^{33} is H; and R^{44} is an optionally substituted C_{3-6} monocyclic heteroaryl containing a N, O or S atom, wherein the optional substituents are R^6 groups; R^6 is R^{50} ; and R^{50} is CH_3 .

Determining the Scope and Content of the Prior Art

Johnson et al. disclose the compound



Johnson et al., STN International, HCAPLUS Database, Columbus, OH, Accession No. 1998:124013, Reg. No. 201857-66-1). Examiner presumes that this compound is in a solvent, which creates a composition.

Art Unit: 1626

Ascertaining the Difference Between the Prior Art and the Instant Application

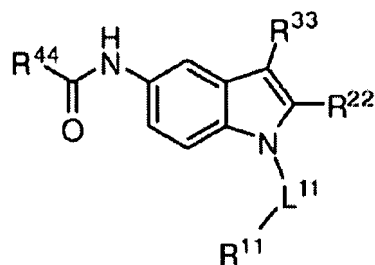
In the instant invention R^{22} is C_{1-6} alkyl. In the prior art, the compound has a hydrogen atom. Thus, the difference is a hydrogen atom and a methyl group.

Finding Prima Facie Obviousness

It is well established that the substitution of methyl for Hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. *In re Wood*, 199 USPQ 137 (CCPA 1978) and *In re Lohr*, 137 USPQ 548, 549 (CCPA 1963). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity.

(2) Claims 25, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartlett et al., US Pat. No. 5,494,911.

The instant invention is drawn to a composition comprising a pharmaceutically acceptable carrier, excipient or diluent together with a compound of the formula,

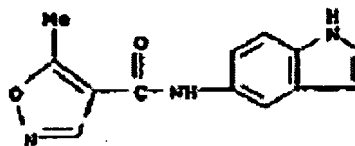


, wherein L^{11} is a covalent bond; R^{11} is H; R^{22} is C_{1-6} alkyl;

R^{33} is H; and R^{44} is an optionally substituted C_{3-6} monocyclic heteroaryl containing a N, O or S atom, wherein the optional substituents are R^6 groups; R^6 is R^{50} ; and R_{50} is CH_3 .

Art Unit: 1626

Determining the Scope and Content of the Prior Art



Bartlett et al. disclose the compound: and

pharmaceutically acceptable carrier (see col. 7, line 54 – col. 8, line 18; and col. 23, Ex. 41).

Ascertaining the Difference Between the Prior Art and the Instant Application

In the instant invention R^{22} is C_{1-6} alkyl. In the prior art, the compound has a hydrogen atom. Thus, the difference is a hydrogen atom and a methyl group.

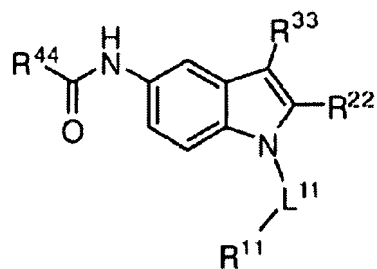
Finding Prima Facie Obviousness

It is well established that the substitution of methyl for Hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. *In re Wood*, 199 USPQ 137 (CCPA 1978) and *In re Lohr*, 137 USPQ 548, 549 (CCPA 1963). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity.

(3) Claims 25, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frederickson et al., US 2005/0124620 A1.

The instant invention is drawn to a composition comprising a pharmaceutically acceptable carrier, excipient or diluent together with a compound of the formula,

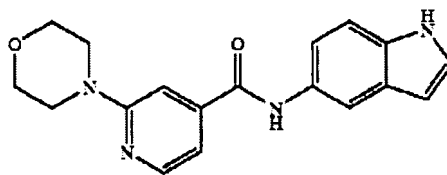
Art Unit: 1626



, wherein L^{11} is a covalent bond; R^{11} is H; R^{22} is C_{1-6} alkyl;

R^{33} is H; and R^{44} is an optionally substituted C_{3-6} monocyclic heteroaryl containing a Nitrogen atom, wherein the optional substituents are R^6 groups; R^6 is halogen, OR^{50} , CF_3 , or C_{6-12} monocyclic heterocycle containing at least one N, O or S atom; and R^{50} is C_{1-3} per fluoro.

Determining the Scope and Content of the Prior Art

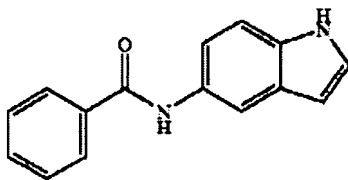


Frederickson et al. disclose the compound:

and

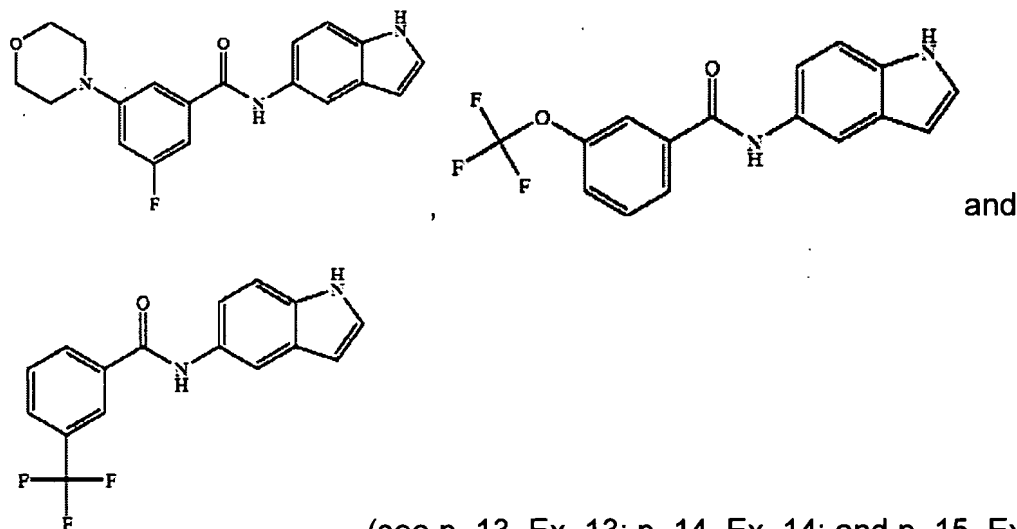
pharmaceutical compositions comprising the compounds (see p. 7, paragraph [0127]; p. 10, paragraph [0170]-[0181]; p. 17, Ex. 23.).

Frederickson et al. also disclose the following compounds which fall outside the



elected genus identified above:

Art Unit: 1626



(see p. 13, Ex. 13; p. 14, Ex. 14; and p. 15, Ex. 16 and 17).

Ascertaining the Difference Between the Prior Art and the Instant Application

In the instant invention R²² is C₁₋₆ alkyl. In the prior art, the compound has a hydrogen atom. Thus, the difference is a hydrogen atom and a methyl group.

Finding Prima Facie Obviousness

It is well established that the substitution of methyl for Hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. *In re Wood*, 199 USPQ 137 (CCPA 1978) and *In re Lohr*, 137 USPQ 548, 549 (CCPA 1963). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity.

Claim Objections

Claims 28-34 and 42-46 are objected to as being dependent on a rejected base claim.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 1626

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

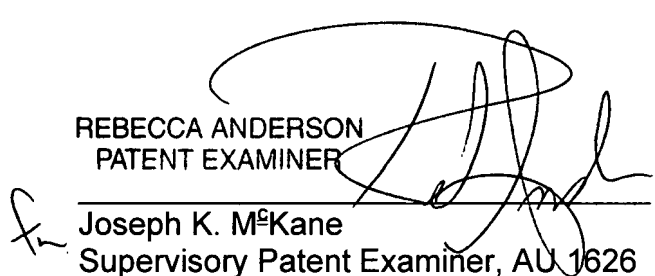
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Art Unit: 1626

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Andrew B. Freistein
Patent Examiner, AU 1626

REBECCA ANDERSON
PATENT EXAMINER


Joseph K. McKane
Supervisory Patent Examiner, AU 1626
Date: June 18, 2007